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reservoir to thereby control the temperature of the fluid circulating in said recirculating fluid loop.--

REMARKS

The examiner has rejected claims 8-18 and has objected to the specification under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling description of the claimed invention:

In particular, claim 8 recites that the heat exchanger replaces a selected (precise) amount of fluid from the recirculating loop with fluid from the reservoir to achieve a selected temperature in the recirculation loop. It is unclear how this is possible. The fluid in the recirculation loop is flowing through a lossy medium, absorbing heat from the external environment. The rate of heat absorption by fluid in the recirculation loop will depend on a variety of factors including the ambient temperature, the body temperature, the flow rate, the size of the patient - which is directly correlatable to the amount of surface area of the pad that contacts the patient, and the amount of fluid in circulation, for example. The exact rate is out of control of applicant. Therefore, applicant is purporting to mix a predetermined amount of fluid at a known temperature with an amount of fluid at an unknown temperature to produce a known temperature. This is not possible. Either the amount of fluid must vary to maintain the predetermined temperature or the temperature must vary.

Claim 8 has been amended in a way that should satisfy the examiner's concerns. Claim 8 now recites that the heat exchanger is constructed to controllably mix fluid from the recirculating loop with fluid from the reservoir. This language is supported by the enabling disclosure provided by in the specification of the application. For example, claim 8 is supported by the summary of the invention:

Within the reservoir housing but external to the reservoir is contained a self-priming fluid pump with a means of exchanging a measured portion of the

recirculation water with water from the reservoir to maintain the circulation water at a desired temperature.
[page 8, lines 8-12]

...
The apparatus maintains temperature control at the therapy site by a controlled dynamic mixing of cold/hot water from the reservoir with the re-circulation water returning from the bladder within the heat exchanger.
[page 8, lines 4-7]

Claim 8 is also supported by the detailed description:

The pump/heat exchanger 13, under microprocessor control, continuously displaces a precise amount of re-circulation water with water from the constant temperature reservoir to precisely maintain the temperature of the circulation water exiting the pump/heat exchanger 13. The displaced re-circulation water is returned to the reservoir via the air/water separator 15 to maintain a constant volume in the circulation system. [Page 17, lines 12-19]

Based on the above disclosure, applicants submit that one skilled in the art can make and use the invention recited in claim 8 without undue experimentation. For this reason, the rejection under 35 U.S.C. § 112, first paragraph, should now be withdrawn.

The examiner has indicated that:

In addition, the examiner notes that on page 11, applicant recites that the rate of fluid exchange in the heat exchange varies. This completely contradicts the claim and the disclosure on page 17, which says that a predetermined fluid amount is added recirculating fluid, as if the mixing rate varies, then a predetermined fluid amount is not being replaced. Further, it is unclear what the predetermined amount of fluid replaced is. In order for one skilled in the art to make and use applicant's invention, the amount of fluid to be replaced must be known.

We are unsure what is intended by the above remarks. Page 17 of the specification recites that:

The pump/heat exchanger 13, under microprocessor control, continuously displaces a precise amount of re-circulation water with water from the constant temperature reservoir to precisely maintain the temperature of the circulation water exiting the pump/heat exchanger 13. [Page 17, lines 12-16]

It appears that the examiner is interpreting this language as teaching that the pump/heat exchanger maintains a fixed temperature in the recirculating fluid loop by displacing a fixed amount of recirculation water with water from the reservoir. This interpretation is not consistent with the plain meaning of the disclosure on page 17, nor is it what was intended, as indicated by the following description of the way in which the therapy temperature may be maintained (emphasis added):

The apparatus maintains temperature control at the therapy site by a controlled dynamic mixing of cold/hot water from the reservoir with the re-circulation water returning from the bladder within the heat exchanger. By using the real-time temperature information generated by the temperature sensing devices, the microprocessor controls the rate of reservoir/re-circulation fluid mixing within the heat exchanger. [Page 11, lines 4-10]

That is, in the embodiment described on page 17, the pump/heat exchanger displaces recirculation water with water from the reservoir in an amount that is controlled based upon measurements from the temperature sensing devices. Thus, there is no contradiction between the disclosure on page 17 and the disclosure on page 11.

The examiner has also indicated that:

Further, it is unclear how the temperature is maintained is the pump is turned off and on to provide tactile stimulation, as it is unclear how any fluid is replaced during these periods (note that page 17 recites that fluid is constantly replaced). Clarification is required.

We submit that the amendments to claim 8 address the examiner's concern expressed by this

remark.

The examiner has also rejected claim 18 and has objected to the specification under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the claimed invention:

Claim 18 recites that the thermistors are positioned such that one is in the fluid entry tube and one is in the fluid return tube. However, on page 14, the last two lines recite that the thermistors are located both on tube 11, which is the fluid entry tube. Therefore, claim 18 lacks a written description in the specification.

Contrary to the examiner's assertion, however, the specification provides sufficient support for the feature of a first temperature sensor monitoring the temperature of fluid entering the therapy pad and a second temperature sensor monitoring the temperature of fluid exiting the therapy pad, as recited in claim 18. As explained in detail below, the specification reasonably conveys to one skilled in the art that applicants had possession of the subject matter recited in claim 18. In particular, the application clearly describes that: (1) the bladder is coupled to a pair of fluid supply lines which, in turn, are coupled to the reservoir housing by "quick disconnect" connectors; (2) a thermistor or other temperature-sensing device is located at or near the quick disconnect of each fluid supply line; and (3) fluid entering the bladder flows through one fluid supply tube and fluid exiting the bladder flows through the other fluid supply tube. Therefore, one temperature sensor monitors the temperature entering the bladder and the other temperature sensor monitors the temperature of fluid exiting the bladder, as recited in claim 18.

(1) The application explains that the bladder is coupled to a pair of fluid supply lines which, in turn, are coupled to the reservoir housing by "quick disconnect" connectors:

Connecting the bladder to the reservoir housing is a pair of fluid supply lines which are terminated at one end by the mating half of the "quick disconnect" connectors mounted in the reservoir housing. [Page 9,

lines 16-19]

(2) The application also explains that a thermistor or other temperature-sensing device is located at or near the quick disconnect of each fluid supply line (emphasis added):

Affixed within the supply line assembly is a pair of thermistors or other suitable temperature-sensing devices, one located in each of the pair of fluid supply lines at or near the quick disconnect mounted in the reservoir housing, the output of which is monitored by the control electronics to implement the closed-loop temperature control of the cold or heat therapy. [Page 10, lines 3-8]

(3) The application further explains that fluid entering the bladder flows through one fluid supply tube and fluid exiting the bladder flows through the other fluid supply tube:

The reservoir 19, pump/heat exchanger 13, supply tubes 41 and 42, and bladder 60 form a fluid circuit in which may flow in either direction. [Page 17, lines 6-8]

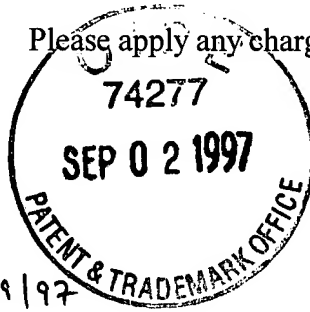
Because fluid entering the bladder flows through one fluid supply tube and fluid exiting the bladder flows through the other fluid supply tube, one temperature sensor monitors the temperature entering the bladder and the other temperature sensor monitors the temperature of fluid exiting the bladder, as recited in claim 18.

For the reasons given above, applicants submit that the application reasonably conveys to one skilled in the art that applicants had possession of the subject matter recited in claim 18 and, therefore, the rejection under 35 U.S.C. § 112, first paragraph, should be withdrawn.

Applicants submit that the claims are in condition for allowance and should now be allowed.

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Respectfully submitted,

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Edouard A. Garcia
Reg. No. 38,461

Fish & Richardson P.C.
2200 Sand Hill Road, Suite 100
Menlo Park, CA 94025

• Telephone: 650/322-5070
• Facsimile: 650/854-0875
•

75928.PAL1